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Jeremy Powell
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Dear Mr Powell,

Re. Single technology appraisal (STA)

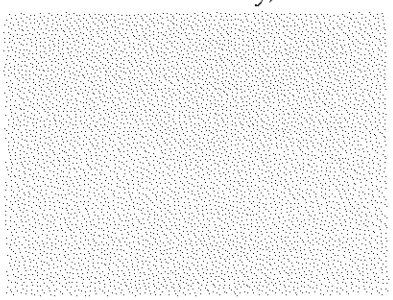
Abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs

Appraisal consultation document

MSD welcomes the opportunity to comment on the ACD and evaluation report for abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease modifying anti-rheumatic drugs.

Please see below our comments on both.

Yours sincerely,



Comments on the Appraisal Consultation Document

Section 3.9

Section 3.9 states that in the Kremer phase 2b and AIM trials, abatacept plus methotrexate led to statistically significant improvements from baseline in the physical and mental components of the SF-36 at 6 months compared with placebo plus methotrexate. We would kindly suggest that it is also noted here that from Kremer phase 2b trials the mental component score for abatacept 2 mg/kg plus methotrexate at one year was not statistically significant.

Section 3.38

MSD supports the preference of the ERG for the hybrid analysis and agrees that 63% represents the vial sharing that occurs with infliximab.

As costs are an integral component of all economic evaluations, it is important that they are estimated as accurately and consistently as possible across Technology Appraisals and reflect NICE's objectives with respect to issuing national guidance (Decision Support Unit Briefing Paper on Costs, A Miners, 2007). Given that vial wastage may have a substantial impact in estimating cost-effectiveness, it is appropriate for NICE to make recommendations that take account of vial sharing.

In their original manufacturer submission (MS), Bristol Myers Squibb (BMS) did not allow for vial sharing for infliximab. MSD feel that this acts to bias results in favour of abatacept and argue that, in line with the ERG's 'Hybrid analysis', there should be at least 63% vial sharing included for Infliximab in the basecase submission for abatacept.

The value of 63% comes from a study which contacted rheumatology pharmacists and nurses nationwide to determine typical clinical practice for vial sharing. 162 centres were contacted to ask the following vial sharing questions:

(1) Do you vial share with infliximab in rheumatology?

(2) What proportion of rheumatology patients received doses of infliximab treatment which have been vial optimised?

The results of these questions were then compiled and analysed to determine the proportion of patients responding to the questionnaire that were vial sharing.

Of the 162 centres contacted, 33% (n=54) responded to the question:

Do you vial share with infliximab in rheumatology? (n=54)

	Number of Patients	Number of Centres	% of total number of patients
Yes	2,047	19	63.04%
No	1,200	35	36.96%
Total	3,247	54	100.00%

MSD therefore strongly urges that evidence from clinical specialists regarding vial sharing be taken into account by NICE in this appraisal and that the Appraisal Committee will take a similar and consistent approach to the issue of vial wastage as that in previous appraisals (TA133[a], TA195[b]).

[a] TA133 Omalizumab for severe persistent allergic asthma, August 2007, available at http://www.nice.org.uk/nicemedia/pdf/FADOmalizumabAsthma.pdf.

[b] TA195 Rheumatoid arthritis - drugs for treatment after failure of a TNF inhibitor, August 2010, available at http://www.nice.org.uk/nicemedia/live/13108/50413/50413.pdf

Comments on the Evaluation Report

Table B80

In table B80 the dose description for golimumab is incorrectly stated as "50 mg every four weeks". The correct wording from the SmPC for golimumab is "50 mg given once a month on the same date each month".